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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,946	10/04/2005	Akiko Itai	P27674	5544
7055 7590 03/06/2008 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER HAYLIN, ROBERT H				
ART UNIT		PAPER NUMBER		
1626				
NOTIFICATION DATE		DELIVERY MODE		
03/06/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com

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# Office Action Summary

## Application No.

10/529,946

## Applicant(s)

ITAI ET AL.

## Examiner

ROBERT HAVLIN

## Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 12-14 and 21-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 14 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 13, and 27-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

**Status of the claims:** Claims 1-8, 12-14, and 21-40 are pending. Claims 1-8, 14, 21-26 were withdrawn. Claims 12, 13, and 27-30 are under examination in this action.

**Priority:** This application is a 371 of PCT/JP03/12648 (10/02/2003) claiming priority to JAPAN 2002-291114 (10/03/2002).

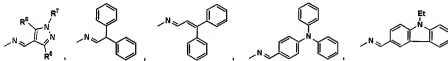
**IDS:** The IDS filed on 10/04/2005 has been considered.

### *Election/Restrictions*

The elected scope of examination includes compounds of the formula



wherein R is one of the following:

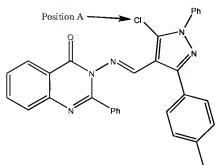


### *Claim Rejections - 35 USC § 103*

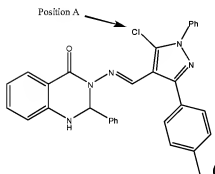
1. Claims 12, 13, 27-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Farghaly et al. (Alexandria J. of Pharm. Sci., 1990, vol 4, p. 52-6) in view of Hadjipavlou-Litina (Curr. Med. Chem., 2000, v. 7, p. 375-388), Bonola et al. (J. Med. Chem., 1970, v. 13, p. 329-332), Kirchner et al. (US 3,843,654), and Kurup et al. (Chem. Rev., 2001, v. 101, p. 2727-2750). This rejection is maintained.

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The claims read on a genus of compounds including the species of



(claims 12, 13, 27, and 28) and

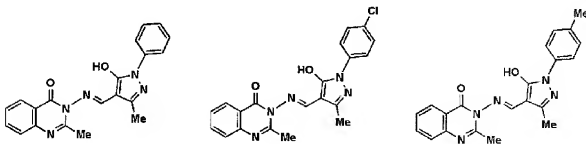


(claims 29 and 30) and compounds where the substitution

at position A (as annotated above) can be halogen, hydroxyl, or C<sub>1</sub>-C<sub>6</sub>-alkoxy which

may be substituted. Claim 12 provides that compounds of group β below are excluded:

[Compound group β]



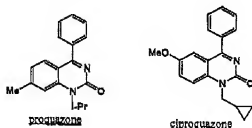
The compounds of this inventions are also stated to have numerous uses including the following from the specification:

Furthermore, according to preferred embodiments of the aforementioned invention, provided are the aforementioned medicament having one or

more actions selected from the group consisting of antiallergic action, antiallergic inflammation, and antiasthmatic action; the aforementioned medicament having an action of preventing the aggravation of brain damage, and/or an action of improving the prognosis of brain damage; the aforementioned medicament having an action of cerebroprotection; and the aforementioned medicament having one or more actions selected from the group consisting of an action of regulating estrous cycle, an action of regulating sleep, an action of thermoregulation, an analgesic action, and an action of regulating olfaction.

Response to Applicant Arguments

1. Applicant claims that the teachings of Hadjipavlou are "clearly structurally different from the compounds of the present invention" and thus there is no motivation or suggestions to combine the references to utilize the QSAR methodologies taught therein. Applicant points out that the reference specifically refers to only two compounds of the formula:



However, the reference clearly is referring to these two compounds as exemplary species of the class of compounds known as "quinazolinones," which are suggested to have anti-inflammatory activity (last paragraph, page 379).

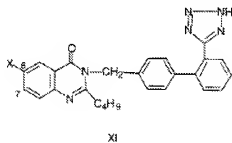
Furthermore, the compounds of the present invention are clearly quinazolinones as the title of the application states. Thus, the compounds are well within the same art-recognized class and are properly considered in an obviousness determination.

2. Applicant is correct in pointing out that the Kurup reference does not specifically teach pyrazole, but instead imidazole. However, the two species are so closely related

that the teachings with respect to the one is reasonably applied to the other.

Furthermore, on page 2748 the reference concludes by stating that the "imidazole/heterocyclic" ring is needed for efficient binding of the drug. Thus, the teachings of the reference do apply to pyrazole derivatives.

In addition, table 11 does show relevant QSAR data pertaining to the closely structurally related pharmaceutical compounds such as:



, including halogen derivatives.

Thus, the Kurup prior art reference was properly included in the obviousness determination because of the close structural similarity to the instantly claimed compounds and even by the fact that the Kurup reference also was exploring R-group variations on the common core of quinazolinones, just as in the instant application.

3. The prior art Bonola, teaches the same structural core as the instant invention AND the reference is investigating the biological activity of the compounds. The reference specifically suggests utilities which are commonly associated with anti-inflammatory agents such as NSAIDs, therefore the reference was properly included in the obviousness determination.

4. The quinazolinones taught by Kirchner are so closely structurally related that one of ordinary skill in the art would certainly look to its teachings when investigating compounds such as those taught by Farghaly. Furthermore, the quinaolinones of

Kirchner are taught to as "exerting pharmacological effects in animal organisms, e.g. barbituate ..." and thus was not limiting in the suggestion of possible uses of the compounds taught and reasonably includes possible anti-inflammatory activity. In addition, even if the particular compound cited in the prior office action was not "proved to have any pharmacological action," the reference teaches the specific compound as a member of a class that does. Therefore, the teachings of Kirchner were properly included in the obviousness determination.

#### ***Conclusion***

All claims are rejected. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner, Art Unit 1626

/Rebecca L Anderson/  
Primary Examiner, Art Unit 1626